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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/551,717

07/14/2006

Dan Gazit

30695

6234

7590
Martin Moynihan
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03/18/2008

EXAMINER

WHITEMAN, BRIAN A

ART UNIT

PAPER NUMBER

1635

MAIL DATE

DELIVERY MODE

03/18/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/551,717	Applicant(s) GAZIT ET AL.	
	Examiner Brian Whiteman	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 87-111 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 87-111 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Brian Whiteman, Art Unit 1635.

The reply (Group IV, now Group II) filed on 12/18/07 to the election/restriction mailed on 9/18/07 is acknowledged, however upon further consideration another election/restriction is required. Thus, the election/restriction mailed on 9/18/07 is vacated in view of the new election/restriction set forth below.

There is more than one nucleotide sequence recited in the instant claims. The Office decision to rescind the 1996 waiver (for examining up to 10 dependent and distinct nucleotide sequences) is based upon the increasing computational, search and examination burden required for the consideration of nucleic acids sequences, and complexity of claims drawn to such, compared to the time of the 1996 waiver. See <http://www.uspto.gov/web/patents/patog/week13/OG/TOC.htm#ref14>.

NOTE: claim 107 depends on a cancelled claim, to expedite prosecution of the case the claim will be considered to be dependent on claim 106.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

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In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 87, 89, 91-94, 96, and 98-104, drawn to a method of regulating an activity of a SMAD protein in a cell by contacting the cell with a polypeptide encoded by a nucleic acid having a nucleotide sequence at least 70% homologous to SEQ ID NO: 1 and/or SEQ ID NO: 2 or SEQ ID NO: 3 and/or SEQ ID NO: 4 capable of stimulating an expression and/or an activity of TAK1 in the cell, thereby regulating the activity of the SMAD protein in the cell.

If group I is elected then a further restriction in nucleotide sequence is required among SEQ ID NO: 1 and/or SEQ ID NO: 2 or SEQ ID NO: 3 and/or SEQ ID NO: 4 as each sequence has a different physical and chemical structure and encodes different protein, therefore, requires different search in commercial database. Applicant is required to elect one Seq ID No in said groups.

Group II, claims 87, 88, 90, 92, 94, 95, 97, 99-102, and 104, drawn to a method of regulating an activity of a SMAD protein in a cell by contacting the cell with single-stranded or double-stranded oligonucleotide which is at least 12 nucleotides in length and is specifically hybridizable with SEQ ID NO: 1 and/or 2 capable of diminishing or abrogating an expression and/or an activity of TAK1 in the cell, thereby regulating the activity of the SMAD protein in the cell.

If group II is elected then a further restriction in single or double stranded oligonucleotide which is at least 12 nucleotides in length and specifically hybridizes with SEQ ID NO: 1, SEQ ID NO: 2, or SEQ ID NO: 1 and 2 as each sequence has a different physical and chemical structure and encodes different protein, therefore, requires different search in commercial database. Applicant is required to elect one Seq ID No in said groups.

Group III, claims 105-111, drawn to a composition comprising an isolated nucleic acid having a nucleic acid sequence at least 70% homologous to a nucleic acid sequence of a nucleic acid selected from the group consisting of SEQ ID NO: 1 and SEQ ID NO: 2, vector and host cell comprising the vector comprising the nucleic acid of the invention.

If group III is elected then a further restriction in nucleotide sequence is required among SEQ ID NO: 1 or SEQ ID NO: 2 as each sequence has a different physical and chemical structure and encodes different protein, therefore, requires different search in commercial database. Applicant is required to elect one Seq ID No in said groups.

Group IV, claims 105-111, drawn to a composition comprising an isolated nucleic acid having a nucleic acid sequence at least 70% homologous to a nucleic acid sequence of a nucleic acid selected from the group consisting of an antisense strand of SEQ ID NO: 1 and an antisense strand of SEQ ID NO: 2, vector and host cell comprising the vector comprising the nucleic acid of the invention.

If group IV is elected then a further restriction in nucleotide sequence is required among an antisense strand of SEQ ID NO: 1, and an antisense strand of SEQ ID NO: 2 as each sequence has a different physical and chemical structure and encodes different protein, therefore, requires

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different search in commercial database. Applicant is required to elect one Seq ID No in said groups.

The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: In the instant case, claims are directed to an agent capable of modulating an expression and/or activity of TAK1 in the cells. Hibuya et al (EMBO J. February 1998, Vol. 17, No. 4, pages 1019-1028, IDS) teach a method of reducing SMAD activity by transfecting a cell with a polynucleotide encoding a kinase negative from of TAK1, which is known to inhibit endogenous signaling of SMAD. The cited art teaches the same method step as claimed in the instant invention. Therefore, the instant technical feature does not contribute over the prior art.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

A telephone call was made to Martin Moynihan on 3/6/08 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

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The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (571) 272-0764. The examiner can normally be reached on Monday through Friday from 6:30 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Douglas Schultz, SPE – Art Unit 1635, can be reached at (571) 272-0763.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

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/Brian Whiteman/

Primary Examiner, Art Unit 1635